REMARKS

The Examiner's thoughtful consideration to this application is sincerely appreciated.

In the Office Action of September 17, 2001, the Examiner rejected Claims 2 - 6 under 35 U.S.C. § 112, paragraph (¶) 1, as containing matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Secondly, the Examiner rejected Claims 2 - 6 under 35 U.S.C. § 112, paragraph (¶) 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Therein, the Examiner considers the recitation of "interaction agent" and "interaction product" indefinite.

Thirdly, Claims 1- 6 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Blank* (U.S. Patent Number 4,533,540).

Lastly, Claims 2 - 6 under 35 U.S.C. § 112, paragraph (¶) 2, were rejected, a second time, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With regards to this second 35 U.S.C. § 112, paragraph (¶) 2 rejection, the Examiner considers the claims *generally* recite a generic

composition of a polymer, solvent, and a method of forming the composition by adding and mixing and evaporating the solvent.

It is believed that the Examiner had intended to reject Claim 1 for purposes of *generality* under 35 U.S.C. § 112, paragraph (¶) 2, simply because this Claim is the only Claim that fits the description that is rejected to by the Examiner (it being the only Claim that recites a polymer, solvent, and a method of forming the composition by adding and mixing and evaporating the solvent). In response and in order to place the application in condition for allowance, Claim 1 has been amended.

By the amendment to Claim 1, the scope of the invention, Applicant's scope is clarified to entail "modified polymers" as defined in the Specification. The amendment is believed to overcome the rejection based on 35 U.S.C. § 112, paragraph 2, for indefiniteness of a previous claim reciting a solvent, a polymer, and method of forming a film in situ upon body tissue.

This reply and amendment result from a sincere analysis of the issues put forth by the Examiner and believe to respectfully overcome the rejections put forth in the Office Action of September 17, 2001.

Reconsideration and allowance of the application are respectfully requested.

AMENDMENT

1. Applicant respectfully requests that Claim 1 be amended in accordance with the "*Clean Version*" and "*Version With Markings*", attached.

No new matter has been added by the amended claim. Instead, Claim 1 has been amended to clearly distinguish Applicant's claims from compositions containing polymers in general (See page 10, lines 4 - 7; page 11, lines 16 - 19; page 23, lines 4 - 11; and page 26, lines 15 - 22; page 27, lines 4 - 9 and 15; and page 28, lines 1 - 5).

ARGUMENTS

Rejection Under 35 U.S.C. § 112, Paragraph 1

Claims 2 - 6 were rejected under 35 U.S.C. § 112, ¶ 1, as unpatentable for failing to convey that the inventor had possession of the claimed invention at the time the application was filed.

The Examiner's attention is respectfully drawn to a passage in the application (Page 13, lines 11 through page 14, line 6):

"The method of the invention also contemplates the steps of (a) ***forming an interaction product by interaction of a substrate polymer*** *(which may include HPC),* ***which is soluble in a non-toxic solvent, and at least one interaction agent,*** *other than an esterification agent (as in the Pomerantz '158 patent),* ***which interacts with the substrate polymer (and possibly with other components of the interaction mixture), to form an interaction product, which is soluble in a non-toxic volatile solvent, but insoluble in body fluids;*** *(b)* ***solublizing the interaction product in a non-toxic volatile solvent;*** *and (c) forming a film in situ on body tissue by applying the solvent solution of the interaction product to body tissue and (d) separating the solvent from the liquid composition. As previously disclosed, the interaction product can be separately manufactured and then solublized in the volatile solvent or, alternatively, the interaction product can be formed in situ, during manufacture and/or storage of the liquid composition or during the application-drying of the liquid composition upon body tissue, or both.*

Our invention also contemplates a liquid composition which forms a medicated film in situ upon body tissue, comprising: (a) a non-toxic volatile solvent; (b) an interaction product formed by interaction between a substrate polymer and an agent other than an esterification agent, which interaction product is soluble in the volatile solvent, but insoluble in body fluids; and (c) a medicinal component, in addition to any other medicament, if any, in the

composition. Also the invention contemplates such a liquid composition, containing such a separate medicament, but in which the substrate polymer is a polymer other than HPC, in which case, the interaction agent can include an esterification agents."

Furthermore, on Page 22, line 11 through Page 25, line 12 of the Specification, the following is provided:

"The invention can be visualized as the use of an ***interaction product comprising a three-part molecule composed of a polymer, a "linker", and a hydrophobic group****, schematically represented as:*

(polymer)-(linker)-(hydrophobic group)

wherein the linker may or may not contain atoms that were originally part of the polymer and/or the hydrophobic group. ***These major constituents of the interaction product molecule consist of:***

(1) a ***polymer****, including synthetic polymers, natural polymers, and synthetically-modified natural polymers, including homopolymers, as well as block, alternating, and random copolymers.*

*(2) a **"linker"** that may consist of organic functional groups that are known to join differing domains of complex organic molecules, including but not limited to esters (O=C_O) and their sulfur derivatives [i.e., thio (S=C_O), thiolo (O=C_S), and dithio (S=C_S) derivatives], ethers (_O_) and their thio derivatives (_S_), urethanes [O_(C=O)_N] and their thio derivatives (e.g., xanthates), carbonates [O_(C=O)_O] and their thio derivatives, amides (O=C_N) and imides and their thio derivatives, ureas [N_(C=O)_N] and their thio derivatives, amines (C_N), imines (C=N), acetals and hemiacetals [RCH(OR')(OR") and RCH(OR')(OH)] and their thio derivatives, ketals and hemiketals [RR'C(OR")(OR'") and RR'C(OR")(OH)] and their thio derivatives, sulfonates [_S(=O)$_2$_O], sulfinates [_S(=O)_O], sulfonamides [_S(=O)$_2$_N], sulfinamides[_S(=O)_N], disulfides (_S_S_) and their various mono- and polyoxides, sulfoxides [R_S(=O)_R'], sulfones [R_S(=O)$_2$_R'], carbon-carbon single or multiple bonds, alcohols [RC(OH)R'], ketones [R_(C=O)_R'] and thioketones [R_(C=S)_R'], phosphate esters [RO_P(=O)(O-)_OR' and RO_P(=O)(OR')(OR")], phosphamides [RO_P(=O)(O-)_NR' and RO_P(=O)(OR')(NR") and RO_P(=O)(NR')(NR") and O=P(NR)(NR')(NR") and their less substituted analogues, e.g., RO_P(=O)(NR')(NH$_2$)], phosphonate esters [R_P(=O)(O-)_OR'], and phosphonamides [R_P(=O)(O-)_NR' and R_P(=O)(NR')NR" and their less substituted derivatives], phosphinate*

esters [R_P(=O)_OR'], phosphinamides [R_P(=O)_NR'], or combinations thereof,

wherein, the various R, R', R", and R"' groups are the polymer and/or hydrophobic groups being linked.

(3) a ***hydrophobic group*** *that may principally derive its hydrophobicity from a hydrocarbon group, including saturated and unsaturated hydrocarbon chains (e.g., terpenes) and rings (i.e., cycloalkyl) and combinations thereof (e.g., steroids), which may contain one or more heteroatoms in the chains and/or rings, or fats, oils, waxes, or from a haloalkyl group, such as a partially or entirely fluoro-substituted alkyl chain [e.g., $(CF_2)_n(CF_3)$] or ring or combination thereof, such groups typically exhibiting greater hydrophobicity than the comparable-length parent unsubstituted hydrocarbon, or from an aromatic or aralkyl group (i.e., combined aromatic and aliphatic constituents), or heterocyclic groups (e.g., furyl, thienyl), or from a silicone (e.g., dimethylsiloxane unit or units) or other heteroatom-containing hydrophobic group, and including any other group with generally recognized hydrophobic character."*

The above description, in summary, contains the following information about the "interaction agent": (1) it is a chemical that facilitates a reaction with a polymer; (2) it does not esterify in the presence of HPC or vinylpyrrolidone; (3) is soluble in a solvent, such as a lower alkyl alcohol[1]; (4) it is insoluble in body fluids; (5) it includes a constituent "linker" reactant; (6) it donates a "linker" group to the subsequent "interaction" product (see Page 23, line 6, through Page 24, line 16, for a list); (7) it includes a constituent "hydrophobic" reactants; and (8) it donates a "hydrophobic" group to the subsequent "interaction" product (see Page 24, line 17, through Page 25, line 12, for a list).

Likewise, the following information about the "interaction product" is disclosed: (1) it is the product of a reaction between the interaction agent and the polymer; (2) is not esterified by the interaction agent in the presence of HPC or vinylpyrrolidone; (3) is insoluble in body fluids; (4) it contains a linker group (See Page 23, line 6, through Page 24, line 16, for a list) that is derived from the interaction agent, combines with the polymer, and combined, contribute to the interaction product; and (5) it contains a hydrophobic group (See Page 24, line 17, through Page 25, line 12, for a list) that is derived from the interaction agent, combines with the polymer, and combined, contribute to the interaction product.

---

[1] The example of lower alkyl alcohol, as a solvent, is provided in the Specification on Page 17, line 2.

It should be apparent that the inventors seek to define two new classes of chemicals for purposes of this application where none existed before, either by convention or other available reference.

In the Specification, following the lengthy description, summarized above, are four (4) specific interaction agents and their respective interaction products described and drawn in detail. Moreover, the Specification ends following seven (7) working examples for disclosing "interaction agents" and the procedure for producing their respective "interaction products".

Moreover, a finite list of the alternative "linkers" and "hydrophobic groups" that can be used in the disclosed invention, provided in quotes above, is testimony that the inventors had reasonably investigated the extent of their invention so as to provide choices of chemical agents and product, as well as, provide operative illustrations and instructions for those skilled in the art to copy the disclosed invention.

Keeping in mind that the issue is whether the inventors had reasonably conveyed to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The measures that the inventors have taken to sufficiently describe the two classes of chemicals ("interaction agent" or "interaction product) by employing characteristics, physical properties of groups within each species ("linker" and "hydrophobic"), four embodiments, and

seven working examples should attest to the inventors' thorough understanding of their invention at the time of filing.

It should be abundantly apparent from the above excerpts, that at the time of filing, the inventors had a clear conception of what possible compounds could qualify within the class of either "interaction agent" or "interaction product".

To limit the invention to interaction agents or interaction products to less than what the inventors have defined as each class would be to unfairly limit the scope of the invention for the following reasons: (A) for the reason that the inventors have invented and described a class of chemicals that previously are unknown under any defined group of chemicals; and (B) for the reason that the invention would be unfairly curtailed by limiting the invention to only the four specifically named interaction agents and their respective interaction agents, when the inventors have disclosed that other molecular variations bearing a discrete set of characteristics, are equally suitable with regards to the overall invention.

REJECTION UNDER 35 U.S.C. § 112, paragraph 2

Claims 2 - 6 were rejected under 35 U.S.C. § 112, ¶ 2, as unpatentable for being indefinite. More particularly, that the recitations, "interaction agent" and "interaction product" are indefinite.

"The test for indefiniteness, is whether one skilled in the art would understand the bounds of the claim when read in light of the Specification... If the claims read in light of the Specification reasonably apprize those skilled in the art of the scope of the invention, § 112 demands no more... The degree of precision necessary for adequate claims is a function of the nature of the subject matter." Miles Laboratories, Inc. v. Shandon Inc., 997 F.2d 870, 27 USPQ 2d 1123 (fed. Cir. 1993), cert. denied, 510 U.S. 1100 (1994).

The issue is whether or not one skilled in the art could distinguish which compounds would fall within the confines of the claimed classes of "interaction agent" or "interaction product".

It is again asserted that the inventors seek to define two new classes of chemicals for purposes of this application where none existed before, either by convention or other available reference.

To this end, the inventors have first, provided a list of "linker" groups that characterize this class. Secondly, the inventors have provided a list of "hydrophobic" groups that characterize this class. Thirdly, specific chemical characteristics have been carefully outlined so as to provide those skilled in the art with defined parameters for defining the two new classes.

It is respectfully asserted that those skilled in the art or in the field of chemistry are sufficiently knowledgeable to be capable of determining from the Specification what compounds contain one of each of the specified "linker" groups and "hydrophobic" groups, and exhibit the physical properties specified in the Specification. Not one of the parameters defining these two classes of chemicals can be considered unduly complicated in light of the level of expertise in the chemical field. On the contrary, physical properties of compounds (e.g. structural geometry, solubility, entropy, etc.) are considered elementary chemistry.

Characteristics include: solubility with a solvent such as a lower alkyl group, insolubility with body fluids, reactivity with a polymer and additive combined, and the exact reaction whereby a linker and hydrophobic group are both transferred from the "interaction agent" to the "interaction product".

Having no available convention, name, or other classification available for distinguishing "interaction agent" and "interaction product", the Applicant has reasonably sought to provide parameters, such as the linking and hydrophobic attached groups and physical characteristics to provide those skilled in the art in distinguishing member from non-member compounds in the classes.

Fourthly, the inventors have provided four (4) examples of possible embodiments wherein in each, different "interaction agents" are shown to react with a polymer, to produce

illustrated "interaction products" (See embodiments numbered 1 - 4, Pages 25, line 19, through Page 28, line 5).

Lastly, in addition to the four (4) embodiments thoroughly described in the Specification, *Supra.*, the inventors provide seven (7) working examples with step-by-step instructions for one skilled in the art to follow for conducting the reaction that combines a polymer and "interaction agent" to produce the "interaction product". (See Examples 1 - 7, Pages 29, line 1, through Page 35, line25)

This amendment seeks to clarify that the inventors have clearly and definitely defined two new classes of chemicals reasonably considering that these classes have not yet been previously defined.

As asserted above, to limit the invention to interaction agents or interaction products to less than what the inventors have defined as each class would be to unfairly limit the scope of the invention for the following reasons: (A) for the reason that the inventors have invented and described a class of chemicals that previously are unknown under any defined group of chemicals; and (B) for the reason that the invention would be unfairly curtailed by limiting the invention to less than the class defined, when the class, as it is defined in the Specification is clearly defined, can be understood by one skilled in the art, and is no larger than what the inventors themselves have discovered and disclosed.

Rejection Under 35 U.S.C. § 102 (b)

Claims 1 - 6 were rejected under 35 U.S.C. § 102(b) as unpatentable over *Blank* (U.S. Patent Number 4,533,540).

The Applicant's disclosure is not anticipated by *Blank's* work for the reason that *Blank* discloses various forms, (e.g. aerosol, tape, cast, film) for sustaining or controlling the administration of a vaso-dilator, and not a composition for protective or medicated films of the body.

A close reading of the prior art reveals that the prior art concerns the control of vaso-dilator's release in the coronary system, exclusively. For example, every one of the prior art's claims and the whole of the Specification are namingly concerned with polyvinylpyrrolidone and nitroglycerin, a coronary vasodilator. The uniformity with which *Blank* emphasizes polyvinylpyrrolidone, used in conjunction with nitroglycerin, is indicative, that the invention is, and aptly named, "NITROGLYCERIN-CONTAINING POLYMERIC MATRIX FOR SUSTAINED RELEASE ON TOPICAL APPLICATION".

The preoccupation of the prior art with controlling the dosage of nitroglycerin is with good reason! Nitroglycerin, when applied as a constant, or *sustained* dose, is considered safe. However, if nitroglycerin dosages should suddenly decrease, then angina (heart) attacks can

result from the change in dosage[2]. Clearly, the need for a composition and method for maintaining a sustained dose of nitroglycerin-like vaso-dilator has welcomed the invention by *Blank*, as it was designed precisely for this purpose!

Nitroglycerine-related vaso-dilators are now well known for preventing acute heart attacks and preventing angina. Sublingual nitroglycerine spray (which is considered most stable) is available, as well as, ointments, patches, oral tablets, and buccal tablets (which are placed between the upper lip and gum), and promoted for longer-term prevention of angina attacks.

While not unique to *Blank's* invention, but notably distinct from the Applicant's invention, is that *Blank's* composition may be administered via: ointment, gel or film in a base such as vaseline, lanolin, and the like.

While patches are clearly revealed in the prior art, *Blank's* invention is immeasurably invaluable because it introduces a controlled dosage that can be empirically and quantitatively distinguished from all previous known patches. The unique aspects of the prior art's disclosure are: (1) polyvinylpyrrolidone is copolymerized with nitroglycerine or other vaso-dilator; and (2) creating a sustained dose of vaso-dilator; and (3) prevents the risk of heart attacks caused by a drop in the dosage of vaso-dilator.

---

[2] Copyright ©© 1999 Nidus Information Services, Inc. Well-Connected Report: Angina and Coronary Artery Disease. September 1999. (Online) www.well-connected.com.

By contrast, the Applicant claims a wear-resistant film - insoluble to body fluids, exclusively, that concerns particular interaction agents for modifying a polymer to the specific properties required in a film insoluble to body fluids. This invention is not just a mere "patch" as has been used previously to administer nicotine, nor does it provide sustained releases of nitroglycerine-type vaso-dilators to prevent heart attacks. Patches and sustained vaso-dilators, for one thing, do not form a skin like barrier that can withstand mucosal secretions. The unique aspects of the Applicant's invention are: (1) insolubility in body fluids; (2) modified polymer as defined in the Specification; and (3) method of transferring a linker and hydrophobic group from an "interaction agent" to the polymer, forming an "interaction product".

Accordingly, Claims 1 - 6 of the Applicant's claims include the element of a "modified polymer...insoluble to body fluids". It is respectfully asserted that this limitation sufficiently distinguishes the Applicant's invention from *Blank's*.

(Second) Rejection Under 35 U.S.C. § 112, Paragraph 2

Claims 2 - 6 were rejected under 35 U.S.C. § 112, ¶ 2, as unpatentable for being indefinite. More particularly, the Examiner communicates that the Applicant's claims, reciting a polymer, a solvent, and a method of composition, are too general. The Examiner

points out that in the prior art, *Blank*, the inventor claimed a singular species of copolymer.

It is believed that the Examiner has meant to reject Claim 1, rather than Claims 2 - 6 for this basis, because only Claim 1 recites a solvent, a polymer, and a method of composition, as the Examiner suggests.

Additionally, Claims 2 - 6 are significantly more limited, and hence less general than Claim 1, because they each specify that the constituent polymer must be reacted with an "interaction agent" as described in the Specification. Since Claims 2 - 6 do not generally claim a solvent, a polymer, and a method of composition, it is believed that the Examiner has inadvertently rejected Claims 2 - 6, rather than Claim 1. Hereinafter, the rejection will be addressed as if it named Claim 1.

If the above adjustment is in fact an erroneous assumption, a notification to this effect, from the Examiner, is requested by the Applicant so that the error may be remedied promptly, by a subsequent Reply.

Claim 1, as it is amended, does not now generally claim a polymer and a solvent. The amended claim more specifically claims a modified polymer. "Modified" should be interpreted in light of the Specification and is described in detail therein. More specifically, the polymer is modified so as to contain a "linker" and "hydrophobic" group. Since each of the groups, "linker" and "hydrophobic", are clearly defined in the Specification, along with the

methodology for modifying a polymer, we believe the broadest claim, Claim 1, to be not so general as to be unpatentable.

The Examiner is requested to reconsider and remove the rejection under 35 U.S.C. § 112, ¶ 2, of Claim 1, for being too general.

REQUEST FOR RECONSIDERATION

The Examiner is respectfully requested to reconsider the objections and rejections set forth in the Office Action of September 17, 2001, in light of the foregoing, and issue a Notice of Allowance. If there are any remaining issues that need to be resolved, it is respectfully requested that a telephone call be placed to the undersigned.

SUMMARY

Having provided a clear description of the classes entitled, "interaction agent" and "interaction product", that those skilled in the art can comprehend, the inventor respectfully believes that the rejections based on 35 U.S.C. § 112, paragraphs 1 and 2, are successfully traversed.

Additionally, Claim 1, has been amended to, we believe, sufficiently claim the composition comprising a solvent and a polymer modified to contain a linker and hydrophobic

group. A list of linker groups and hydrophobic groups are specified in the Specification. The chemical means for combining an interaction agent with a polymer and a solvent to produce an interaction product that is soluble in the solvent, however, insoluble in body fluids, is, we believe, sufficiently disclosed to enable one skilled in the art.

Lastly, we urge that the cited prior art disclosure, *Blank* (U.S. Patent Number 4,533,540), does not suggest by inference, or otherwise disclose, a composition for a film, insoluble to body fluids, comprised of groups derived from an interaction agent.

Accordingly, we respectfully urge that the rejections based on §102 and §112, paragraphs 1 and 2, be removed and an issue of Allowance be granted.

Respectfully submitted,

DRUMMOND & DUCKWORTH

William H. Drummond
Registration No. 20,590
Attorney for Applicant
Telephone: (949) 724-1255

VERSION WITH MARKINGS TO SHOW CHANGES MADE
Serial No. 09/509,237

1. The method of forming a film *in situ* upon body tissue, comprising:

(a) applying to body tissue a liquid composition, comprising

(1) a volatile solvent,

(2) a modified polymer, other than an esterified HPC, which is soluble in said solvent, but insoluble in body fluids;

and

(b) vaporizing said solvent from said liquid composition.